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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,756	05/20/2004	Anthony C. Ross	80100.034US2	7358
30328	7590	09/22/2005	EXAMINER	
JONATHAN SPANGLER NU VASIVE, INC. 4545 TOWNE CENTRE COURT SAN DIEGO, CA 92121			NUTTER, NATHAN M	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/849,756	ROSS ET AL.	
	Examiner Nathan M. Nutter	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 July 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 May 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

This application has been re-assigned to Examiner Nathan M. Nutter in Art Unit 1711. All inquiries regarding this application should be directed to Examiner Nutter at telephone number 571-272-1076.

### ***Election/Restrictions***

Applicant's election without traverse of Group II, claims 16-20, in the reply filed on 13 July 2005 is acknowledged.

Applicant has cancelled the claims drawn to the non-elected invention and has added claims 21-38, drawn to embodiments of the elected invention.

Claims 16-38 are pending.

### ***Claim Interpretations***

The recitation of "for use in surgery," as added to claim 1 at lines 1 and 2, is considered as an intended use only. Any composition comprising the constituents as herein recited would inherently possess the same characteristics, and, thus, have the same uses, one use being "in surgery." Further, applicant's assertion that dentistry is not a surgical practice is not taken seriously since a sterile environment is required for root canals to prevent re-infection. Note in Manschedel (US 6,126,446), previously cited, at column 2 (lines 46-54). Regardless, if a skilled artisan were desirous of using a composition within the confines or adjacent to exposed tissue, one would know to sterilize such composition.

### ***Response to Amendment***

The following is placed in effect:

The rejection of claims 16, 19 and 20 under 35 U.S.C. 103(a) as being unpatentable over Mannschedel (US 6,126,446) in view of Shoher et al (US 5,272,184), is hereby expressly withdrawn.

The rejection of claims 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Mannschedel (US 6,126,446) in view of Shoher et al (US 5,272,184), and further in view of Kosegaki et al (US 4,569,736), is hereby expressly withdrawn.

The following new grounds of rejection are being made.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mannschedel (US 6,126,446), previously cited, taken with Futami et al (US 4,740,245), newly cited, Shoher et al (US 5,272,184), previously cited, and Levy (US 6,395,029), newly cited, all in further view of Qin et al (US 6,506,333), newly cited, and Furuta et al (US 5,182,151), newly cited.

The reference to Mannschedel (US 6,126,446) teaches the manufacture of a composition suitable for the use in dental procedures that may comprise "trans-polyisoprene, gutta-percha, balata or a mixture thereof," with titanium dioxide, wax and a zinc compound, as recited and claimed herein. Note column 2 (lines 3-9) for the resin, column 3 (lines 1-20) for the filler materials, (lines 20-31) for the compositional

limitations and (lines 53-59) for administration thereof with a syringe. The zinc component is taught at column 4 (lines 15 et seq.). The reference to Futami et al (US 4,740,245) teaches the production of dental filling composition and shows the use of polyisoprene with titanium oxide, zinc compounds, and wax, as recited and claimed. Note column 2 (lines 57 et seq.) for the resin, column 4 (lines 16-20) and column 6 (lines 46-53) for the use of wax and other resins, column 4 (lines 40-63) for the filler material that may comprise titanium dioxide and zinc compounds, and the paragraph bridging column 4 to column 5 for the amount of the filler to be up to 50 % by weight. The reference to Shoher et al (US 5,272,184) teaches the production of a dental composite which at column 3 (lines 17-23) may comprise "isoprene polymer," as well as metal particles and wax at the paragraph bridging column 2 to column 3. The metal particles may comprise gold and zinc at column 4 (lines 1-12), may be present at a level up to 75% of the final composition and may have an average particle size of between 2 and 80 microns, as taught at column 4 (lines 19-41). The reference to Levy (US 6,395,029) shows the production of a sustained release matrix which may be an implant at column 5 (lines 11-16) and may comprise polyisoprenes at column 12 (lines 41-67), gold at column 13 (lines 1-8) which is taught as "advantageous...for inhibiting inflammation...and inhibiting infection." The composition, itself, may be present as microspheres or nanospheres at column 13 (lines 30-48) and would embrace the particle sizes recited in the instant claims. The employment of titanium and waxes is shown at column 14 (lines 14-28). The reference to Qin et al (US 6,506,333) teaches the use of gamma rays, as a radiation source, for the sterilization of polyisoprene

compositions. Note column 6 (lines 1-36). Claim 2 of the reference teaches the "sterilization dosage of radiation (to be) from about 15 to about 45 kGys," as recited and claimed herein in claims 17, 18, 28, 29, 34 and 35. The reference to Furuta et al (US 5,182,151) is relied upon solely to show the employment of titanium whiskers as an inorganic filler material in a thermoplastic resin composition that may otherwise include elastomers. Note column 18 (lines 24-32) wherein it is taught the use of fiber/whisker additives to enhance physical and mechanical characteristics.

Each of the references to Manschedel (US 6,126,446), Futami et al (US 4,740,245), Shoher et al (US 5,272,184) and Levy (US 6,395,029) are drawn to biocompatible composites of a rubber constituent, as claimed herein, with gold or titanium, as well as wax, other included resins and zinc compounds. All of these components are taught to be conventional. The combination of the several ingredients of the formulation, due to the number of required constituents, necessarily would not be found within the confines of a single reference. The reference to Qin et al (US 6,506,333) teaches the conventionality of the sterilization procedure, as recited herein. Furuta et al (US 5,182,151) is relied upon solely to show the known and conventional use of titanium whiskers in a composition for enhancement of characteristics of that composition. The actual form and size of the filler, as recited in claims 24 and 25, whether it be the titanium or gold constituent, would be a judgment within the skill of an ordinary artisan depending on use and desired firmness, flexibility, or other characteristics depending upon end use. The reference to Furuta et al (US 5,182,151) is relied upon solely to show the use of titanium whiskers in a thermoplastic composition.

Note column 18 (lines 24-32). The reference to Shoher et al shows the particle size for fillers of compositions of this type to be "between 2 and 80 microns," at column 4 (lines 21-31) and shows teaches manipulation of these sizes. Similar compositions, shown by Mannschedel, Futami et al and Levy would be expected to have similar size limitations, since they may be employed in identical capacities. The employment of a syringe for delivery of these compositions, as recited in claims 20, 31 and 37, is shown by Mannschedel at column 3 (lines 53-59) and would appear to be suitable regardless of the filler, i.e. titanium or gold, used. As such, the instant claims would have been obvious to a practitioner having an ordinary skill in the art absent any showing of unexpected results.

***Response to Arguments***

Applicant's arguments with respect to claims 16-20 have been considered but are moot in view of the new grounds of rejection.

Due to the new grounds of rejection, this action is not being made FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan M. Nutter whose telephone number is 571-272-1076. The examiner can normally be reached on 9:30 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nathan M. Nutter  
Primary Examiner  
Art Unit 1711

nmm

16 September 2005